

REMARKS

Claims 1-95 are pending, claims 1-59 are withdrawn, claims 60-95 are rejected and claims 60, 67, 75 and 86 are herein amended. Amendments to the claims are made to more specifically point out and distinctly claim the subject matter regarded as invention. Such amendments should in no way be construed as acquiescence to any of the Examiner's rejections and were made solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

No new matter has been added by virtue of the amendments, support being found throughout the specification and claims as originally filed. Reconsideration is requested, at least for the reasons discussed herein.

Rejection of the claims under 35 U.S.C. §112, first paragraph, written description

Claims 60, 67, 75, 86 and the claims dependent thereon (61-66, 68-74, 76-85 and 87-95) are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, has possession of the claimed invention. Specifically, the Examiner asserts that the specification does not describe how one sample to be separated into components can differ in the amount of female vs. male cells over time and how a maximum in a curve is determined.

Applicants respectfully traverse the rejection.

Claim 60 is directed to a method for treating a specimen of semen containing sperm cells to increase the relative number of sperm cells of a preferred sex type. The method entails separating the semen into two components; a first component having a higher number of sperm of the preferred sex type and a second component having a higher number of sperm of the non preferred sex type relative to sperm of the preferred

sex type. The separation step is performed in a window of time that can be determined by locating a maximum (e.g., maximum percent of female cells) in a curve obtained by plotting the percent of female cells determined by FISH against the percent cells that are Koo positive for aliquots of a sample separated at varying times, thereby determining the time at which the maximum percent female cells occurs. Furthermore, the claimed separation step begins no earlier than about one hour before the time of the maximum percent of female cells. Independent claims 67, 75 and 86 are directed to similar methods which utilize a window of time that can be determined by locating a maximum (e.g., maximum percent of female cells) in a curve obtained by plotting the percent of female cells determined by FISH against the percent cells that are Koo positive and beginning the separation step no earlier than about one hour before the time of the maximum percent female cells.

The Examiner asserts that "[i]t is not described in the specification how one sample to be separated into two components can differ in the amount of female vs. male cells over time . . ." and that [a]pplicant appears to be claiming using the FISH analysis to track when more female sperm cells are present in a single sample, for which there is no scientific support . . ."

It appears the Examiner does not fully comprehend the claimed invention. The Applicant is not asserting that an **unseparated** sample differs in the amount of female vs. male cells over time, although this may be possible, e.g., preferential cell death of female or male cells. Rather, the amounts (percentages) of female vs. male cells differs over time in a **separated** sample; a result of Y-bearing sperm's ability to adhere to cell binding agents in greater proportion than X-bearing sperm and the discovery that this difference is most pronounced during a specific window of time. Thus, this discovery allows for the greater separation of Y and X-bearing sperm during this window. This differential binding ability of Y- vs. X- sperm is evident throughout the application as filed, and specifically illustrated in Example 1 and the related data of Tables 1 & 2. Paragraph 13 of the publication explains this discovery:

We have discovered that there is a period of time, i.e., a sexing window, during **which Y-chromosome bearing sperm develop an ability to**

adhere or bind to cell binding agents in greater proportion than X-chromosome bearing sperm. If the spermatozoa are treated with a cell binding agent in this window, Y-chromosome bearing sperm will adhere or bind preferentially to a cell binding agent whereas X-chromosome bearing sperm will remain preferentially in the fluid. Thus, **separating the cell binding agent with preferentially bound Y-chromosome bearing sperm will remove Y-chromosome bearing sperm preferentially leaving a higher percentage of X-chromosome bearing sperm, thereby biasing the remaining non bound sperm for producing female offspring when introduced into a suitable fertile mammal.** [Emphasis added]

The reason for Y-sperm's preferential binding and, in particular, the change in this binding over time is not fully understood, but is not necessary for patentability. The Federal Circuit has held that an inventor need not understand how his invention works (*Cross v. Iizuka*, 753 F.2d 1040, 224 U.S.P.Q. 739 (Fed. Cir. 1985), ". . . it is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests, nor is the inventor's theory or belief as to how his invention works a necessary element in the specification to satisfy the enablement requirement of 35 U.S.C. § 112." (at 741, footnote 3), citing *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983)).

Nonetheless, while not being bound by theory, it is hypothesized that this change in binding (e.g., Koo antibody binding) over time may be the result of one or more of the following; increased antigen expression post collection, and/or continued development of the "sticky patch" (See paragraph 28 of the publication), and/or unmasking of a binding antigen on the cell, e.g., through the loss of another molecule which masks the binding antigen. Thus, the application clearly teaches how the ratio of male to female sperm in fractionated samples can change over time.

The Examiner stated that the specification does not describe how a window is determined and specifically how a maximum time is determined. Applicants respectfully disagree. The application is rich with written description for the claimed method. The specification includes working examples (e.g., Examples 1 and 3) and detailed protocols (e.g., starting at paragraph 86 of the publication and continuing to paragraph 173) which fully describe the method.

Paragraph 15 of the publication teaches the upper and lower limits for the window:

The window opens when a sufficient number of sperm cells exhibit the sticky patches so that separation preferentially removes sufficient Y-chromosome bearing sperm so that the remaining non bound sperm is biased to a desired level with X-chromosome bearing sperm. The window closes when a sufficient number of sperm cells exhibit the sticky patches so that separation can no longer provide the desired biased level. [Emphasis added]

Furthermore, the application states that the upper and lower limits of the window can be determined by Koo staining:

In certain preferred embodiments of the invention, the window opens with the appearance of the sticky patches on at least about 20% of the sperm cells in the semen, preferably at least about 25%, and more preferably at least about 30%, as determined by labeling the sperm with Koo antibody. The window closes when more than more than 40% of the sperm cells have sticky patches, preferably more than 35%, as determined by labeling the sperm with Koo antibody.

Furthermore, the window can also be determined by locating the maximum in a curve obtained by plotting percent female cells (e.g., as detected by FISH) of a separated sample vs. the percent of cells positive for Koo staining. Applicants have shown that samples separated after different time intervals post collection, contain varying proportions of viable male and female cells as determined by FISH. By plotting the number of female cells or male cells vs. time at a particular temperature in the fractionated population, one can determine a maximum in the number of female or male cells vs. time at that particular temperature. By observing the actual maximum (e.g., maximum % of female cells; See Figs. 2-6), one can determine the optimum time for the methodology being utilized. Figures 2-6 and Example 1 illustrate that a maximum percent of cells can be determined by FISH on a separated sample.

Specifically, in a preferred embodiment, the window is identified in the specification by contacting the samples (i.e., aliquots taken at various times after collection of the semen) with a binding agent (e.g., Koo antibody, which preferentially binds the Y-sperm) allowing the separation of the bound sperm from the non-bound sperm which remains in the fluid. FISH may then be performed on the unbound sperm in the fluid (e.g., Table 2). When these results are plotted, it is readily apparent that, during a specific window of time, the liquid

sample will exhibit a significantly higher percent of X-sperm (as determined by FISH) than Y-sperm. This maximum percent of X-sperm is readily apparent on the Koo vs. FISH graphs of Figs. 2-4 which illustrated the data in Table 1 (percent of cells ICC positive with Koo) plotted against the data of Table 2 (percent of female cells in the fluid after separation as assayed by FISH). As observable in each graph there is a point at which the maximum number of X-sperm remain in the fluid. It is this point at which performing the separation protocol is optimal in order to isolate the X-sperm.

The Examiner also asserts that, "it appears as if the FISH analysis is merely a measure of time and temperature compared to the staining process, i.e., the optimum time and temperature at which the ICC positive cells are stained, not a determination of when more female sperm exist in a sample." This is incorrect.

All Koo and FISH staining were performed under consistent time and temperature conditions (See Example 1). For example, there is no difference in the incubation time or temperature of the Koo staining protocol performed on the sample taken at either the two hours post collection or 12 hours post collection times (See Tables 1 and 2). Only the sample being stained is fractionated at varying times after semen collection.

In light of the above, it is clear the claims are fully supported by the application as filed. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 60, 67, 75, 86 and the claims dependent thereon (61-66, 68-74, 76-85 and 87-95), under 35 U.S.C. §112, first paragraph for alleged lack of written description.

Rejection of the claims under 35 U.S.C. §112, first paragraph enablement

Claims 60, 67, 75, 86 and the claims dependent thereon (61-66, 68-74, 76-85 and 87-95) are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. This rejection is very much interrelated with the with the written description rejection discussed above.

Applicants respectfully traverse the rejection.

The arguments presented above address most of the issues the Examiner raised with respect to enablement. Thus, rather than rehash the arguments presented above Applicants direct the Examiner to the above arguments which support both written description and enablement of the claims. Only those issues raised in the enablement rejection which are not fully addressed above will be discussed below.

The Examiner asserts:

Further, applicants specification, examples, Tables, etc only practice the invention with the female cells being the preferred sex type, not at all enabling one to obtain a preferred **male** sample. Moreover, the examples provided do not support obtaining a preferred male sex type in applicants claimed method. Thus, in view of the lack of any specific guidance with respect to how to obtain a male preferred sex type using applicant method, one skilled in the art would expect a trial and error process to determine how such a preference can be analyzed using such method and how determining such would apply to the as disclosed application, and would further have to determine through undue experimentation, without guidance from the specification, how to obtain a male population using the steps and methods of the invention.

Applicants respectfully disagree.

Based on the teachings in the application and what was known in the art, the application clearly enables one skilled in the art to practice the claimed invention to obtain a preferred male sample. As discussed above, the sperm cell sample can be separated into two fractions (bound and unbound) by utilizing the cell binding agent. In a preferred embodiment, the bound cell fraction preferentially includes Y-sperm and the

liquid cell fraction preferentially includes X-sperm. Thus, the application teaches the preferential isolation of both male (Y-sperm) and female cells (X-sperm). In selecting for a preferred male phenotype the binding agent bound sperm is selected for in vitro fertilization rather than the unbound sperm (female). Thus, the techniques for the preferential selection of male vs. female sperm are essentially identical except that the male sperm are obtained from the bound fraction.

The method for obtaining a preferred male sperm fraction is taught thought the application, including, for example, paragraph 22 of the publication: "[t]he desired or preferred sex can vary with application. Also, the selected sperm cells can be either the bound cells or the non bound cells, depending on the application."

Furthermore, paragraph 64 states:

bound sperm cells also can be recovered, thus, providing separation and isolation of the two populations of spermatozoa (i.e., X-and Y-bearing sperm). Recovery of the magnetic component is easily performed by removing the separation container from the magnetic separator and then draining the container. **Reversal of the binding is accomplished in the same manner as in certain types of chromatography or antibody-antigen reactions.** [Emphasis added]

Thus, it is clear that, based on the specification and what was known in the art at the time of filing, one of ordinary skill could practice the claimed invention without undue experimentation. In light of the above, Applicants respectfully request the Examiner reconsider and withdraw the rejection of claims 60, 67, 75, 86 and the claims dependent thereon (61-66, 68-74, 76-85 and 87-95) under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement.

Rejection of the claims under 35 U.S.C. §112, second paragraph

Claims 60, 67, 75, 86 and the claims dependent thereon (61-66, 68-74, 76-85 and 87-95) are rejected under 35 U.S.C. 112, second paragraph, for allegedly being indefinite. The Examiner alleges that it is unclear how a sperm sample can produce more female than male sperm, what the curve is, how the window of time is determined, whether applicant is separating/sorting by FISH or by a different method and whether or not FISH is necessarily required by the method.

Applicant respectfully traverses the rejection.

It is believed that Applicants' response to the written description rejection above has clarified these issues, and specifically refer the Examiner to the arguments presented therein.

Rejection of the claims under 35 U.S.C. §102

As the Examiner is well aware in order to anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure § 2131:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). "The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)."

Claims 60, 61, 63 and 75 are rejected under 35 U.S.C. 102(b) over Sills et al. (American Journal of Reproductive Immunology, vol. 40, 1998; "Sills"). Sills concludes that:

[t]he expression of H-Y antigen has a slightly higher frequency in human sperm containing the Y-chromosome, but its expression among X-chromosome-bearing sperm also is considerable. Current immunological techniques relying on this antigen are unlikely to effect sex selection of human sperm.

Thus, Sills **fails** to teach or suggest a method for treating a specimen of semen containing sperm cells to increase the relative number of sperm cells of a preferred sex type in a treated specimen to increase the potential for conceiving an offspring of the preferred sex, as claimed herein.

Sills also **fails** to teach or suggest a method that includes:

separating the semen into two components comprising a first component having a higher number of sperm of the preferred sex type than sperm of a non preferred sex type and a second component having a higher number of sperm of the non preferred sex type relative to sperm of the preferred sex type,

as claimed herein.

Further, Sills **fails** to teach or suggest a method

wherein the separating step is performed in a window of time that can be determined by locating a maximum in the curve obtained by plotting percent female cells determined by FISH against percent Koo positive cells for aliquots of a semen sample taken at various times after collection, determining the time at which the maximum percent female cells occurs, and beginning the separation step no earlier than about one hour before the time of the maximum percent female cells.

Thus, it is not seen how the presently claimed invention is anticipated by Sills. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Sills.

Claims 60-62, 67-69, 82-83, 86-91 and 93 are rejected under 35 U.S.C. 102(b) over Benjamin (US 6153373). Although Benjamin '373 describes a method for increasing the percentage of mammalian offspring of either sex by contacting a sperm

sample with an antibody specific to a selected spermatozoa type, Benjamin ***fails*** to teach or suggest that a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex, the increase being compared to separation performed outside the window. Indeed, Benjamin '373 does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Benjamin '373. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '373.

Claims 60-62, 67-69, 82-83, 86-91 and 93 are rejected under 35 U.S.C. 102(a) and (e) over Benjamin (US2003/0068654A1). Although Benjamin '654A1 describes a method for increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, Benjamin ***fails*** to teach or suggest that a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. Indeed, Benjamin '654A1 does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Benjamin '654A1. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1.

Claims 60-62, 67-69, 82-83, 86-91 and 93 are rejected under 35 U.S.C. 102(a) and (e) over Benjamin (6489092). Although Benjamin '092 describes a method for increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, Benjamin ***fails*** to teach or suggest that a window of time after ejaculation can be determined for

performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. Indeed, Benjamin '092 does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Benjamin '092. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '092.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. 102(b) over Blecher et al (US2001/0041348 A1; "Blecher"). Although Blecher describes a method for separating semen into male and female determining sperm with antibodies bound to carriers, such as beads, specific for sex-chromosome molecules, Blecher *fails* to teach or suggest that a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. Indeed, Blecher does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Blecher. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Blecher.

Claims 60-62, 67-69, 75 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Zavos et al. (4999283). Zavos et al. *fails* to teach or suggest determining a window of time after ejaculation and using the identified window of time for performing the separation step to obtain an increase in the percentage of mammalian offspring of either sex. Indeed, Zavos et al does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Zavos et al. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Zavos et al.

Claims 60-62, 67-69, 73 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Van den Bovenkamp (3687806). Van den Bovenkamp *fails* to teach or suggest determining a window of time after ejaculation and using the identified window of time for performing the separation step to obtain an increase in the percentage of mammalian offspring of either sex. Indeed, Van den Bovenkamp does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Van den Bovenkamp. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Van den Bovenkamp.

Claims 60-63, 67-70, 75-80, 82-83, 86-91 and 93 are rejected under 35 U.S.C. §103(a) over Benjamin '654A1 or Benjamin '373 or Benjamin '092 in view of Sills (AJRI, vol. 40, 1998). The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male vs. female sperm cells in a sample. Applicants agree. However, that is not the presently claimed invention.

The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Not one of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Sills, or their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Sills, or any combination of them.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. §103(a) over Belcher '348A1 in view of Sills. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Blecher nor Sills, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Blecher or Sills, or any combination of them.

Claims 60-62, 67-69, 75 and 82 are rejected under 35 U.S.C. §103(a) over Zavos et al. (US 4999283; "Zavos") in view of Sills. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Zavos nor Sills, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window for performing a

separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Zavos or Sills, or any combination of them.

Claims 60-62, 67-69, 73 and 74 are rejected under 35 U.S.C. §103(a) over Van den Bovenkamp (US 3687806) in view of Sills. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Van den Bovenkamp nor Sills, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Van den Bovenkamp or Sills, or any combination of them.

Claims 60-63, 67-70, 75-80, 82-83, 86-91 and 93 are rejected under 35 U.S.C. §103(a) over Benjamin '654A1 or Benjamin '373 or Benjamin '092 in view of Johnson (Reprod. Fertil. 1995). The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male vs. female sperm cells in a sample. Applicants agree. However, that is not the presently claimed invention.

The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes

that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Not one of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Johnson, or their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Johnson, or any combination of them.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. §103(a) over Belcher '348A1 in view of Johnson. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Blecher nor Johnson, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Blecher or Johnson, or any combination of them.

Claims 60-62, 67-69, 75 and 82 are rejected under 35 U.S.C. §103(a) over Zavos in view of Johnson. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo

positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Zavos nor Johnson, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Zavos or Johnson, or any combination of them.

Claims 60-62, 67-69, 73 and 74 are rejected under 35 U.S.C. §103(a) over Van den Bovenkamp in view of Johnson. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Van den Bovenkamp nor Johnson, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Van den Bovenkamp or Johnson, or any combination of them.

Claims 60-63, 67-70, 75-80, 82-83, 86-91 and 93 are rejected under 35 U.S.C. §103(a) over Benjamin '654A1 or Benjamin '373 or Benjamin '092 in view of Spaulding (US 5021244). The Examiner states that it would have been obvious to one of ordinary

skill in the art at the time the invention to cool the semen after collection. However, embodiments of the presently claimed invention are more than merely cooling the semen.

The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Not one of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Spaulding, or their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Spaulding, or any combination of them.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. §103(a) over Belcher '348A1 in view of Spaulding. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Blecher nor Spaulding, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Blecher or Spaulding, or any combination of them.

Claims 60-62, 67-69, 75 and 82 are rejected under 35 U.S.C. §103(a) over Zavos in view of Spaulding. The present invention provides a window for performing a separation of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Zavos nor Spaulding, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention provides a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Zavos or Spaulding, or any combination of them.

Claims 60- 62, 67-69, 73 and 74 are rejected under 35 U.S.C. §103(a) over Van den Bovenkamp in view of Spaulding. The present invention provides a window for performing a separation into of the semen sample into male-rich and female-rich components. The specification describes that the window can be determined by using FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to determine the window. None of the cited prior art teach or suggest such a window of time. Neither Van den Bovenkamp nor Spaulding, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain an increase in the percentage of mammalian offspring of either sex. The present invention uses a window

for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Van den Bovenkamp or Spaulding, or any combination of them.

In view of the discussion above, applicant respectfully submits that the pending application is in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Dated: 12/31/07

Respectfully submitted,

By Jeffrey L. Kopacz/
Jeffrey L. Kopacz
Registration No.: 54,744
EDWARDS ANGELL PALMER & DODGE
LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 439-4444
Attorneys/Agents For Applicant